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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,658	01/11/2002	Ken-Ichi Yamamura	04853.0088	4644

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EXAMINER

QIAN, CELINE X

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 09/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/030,658

Applicant(s)

YAMAMURA ET AL.

Examiner

Celine X Qian

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-18 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Claims 1-18 is pending in the application.

Election/Restrictions

Applicant's election with traverse of species A in the reply filed on 2/23/04 is acknowledged. The traversal is on the ground(s) that the Examiner has not established that there is a lack of unity of invention as required by 37 CFR 1.475 because the Examiner fails to list the different groups of claims and explain why each group lacks unity with other group specifically describing the unique technical feature in each group. Applicants thus request withdrawal of this restriction requirement since the requirement is technically deficient.

Applicants' argument has been fully considered and deemed persuasive. The previous restriction requirement is withdrawn. Upon further reviewing of the claims, they are re-grouped as following, and the reasons for lack of unity are given below. The Examiner apologizes for the inconvenience that may result from this second restriction requirement.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-12, drawn to a trap vector containing a lox P sequence composed of inverted repeat sequence 1, a spacer sequence and inverted repeat sequence 2, wherein the lox P is a mutant lox P, an embryonic stem cell comprising said trap vector and a method of gene trapping by introducing the trap vector into embryonic stem cells.

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Group II, claim(s) 13-18, drawn to a transgenic or knockout animal into which the trap vector is introduced and method of making said transgenic or knockout animal.

The inventions listed as Groups I-II do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. Each group has a unique special technical feature which is not shared by the other group. The special technical feature of Group I is a trap vector, which is different from the special technical feature of Group II. The special technical feature of Group II is a transgenic animal, which is different from the special technical feature of Group I. Therefore, the unity of invention does not exist between the claims of Groups I-VI.

Further, this application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Species (a) SP-SA-lox71-IRES-M-loxP-PV-SP

(b) SP-lox71-IRES-M-loxP-PV-SP

(c) SA-lox71-IRES-M-loxP-PA-PV-SP

(d) SA-lox71-IRES-M-loxP-puro-pA-PV-SP

(e) lox71-M-loxP-pA-lox2272-PV-lox511

(f) lox71-IRES-M-loxP-pA-lox2272-PV-lox511

(g) (lox71-integrated SA)-M-loxP-pA-lox2272-PV-lox511

(h) (lox71-integrated SA)-IRES-M-loxP-pA-lox2272-PV-lox511

(i) (lox71-integrated SA)-M-loxP-pA-lox2272-promoter-M-lox511-SD.

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The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

This species election is made following PCT rule 13.2 under Markush Practice. Such practice requires that "...B(1) a common structure is present, i.e. a significant structural element is shared by all of the alternatives..."(see MPEP Annex B) These species lack unity of invention because they do not share a significant structural element. Since the structure of a significant portion of the vector, including SA, SD, M and PV, is unknown, the vectors are not considered to share a significant structure element. Therefore, the unity between the species does not exist.

Applicant is advised that the reply to this requirement to be complete must include an election of one group of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Further, Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

7, 8, 11-18.

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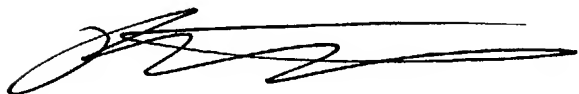
The following claim(s) are generic: 1-6, 9 and 10.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine Qian, Ph.D.

A handwritten signature in black ink, appearing to be 'Celine Qian', with a long horizontal flourish extending to the right.